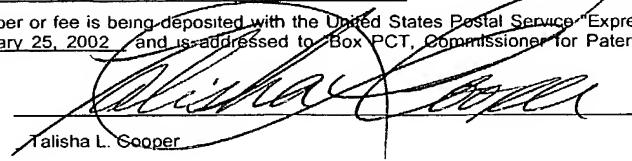


FORM PTO 1390 (REV. 12-29-99)		U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER DHN/322/PC/US	
INTERNATIONAL APPLICATION NO.		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/069081</b>	
PCT/EP00/07204		INTERNATIONAL FILING DATE July 26, 2000	
PRIORITY DATE CLAIMED July 27, 1999			
TITLE OF INVENTION <b>Orthopedic Bone Cement Mixing Container</b>			
APPLICANT(S) FOR DO/EO/US <b>David Foster, Anthony Jones and Rebecca Eveleigh</b>			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
1.	<input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.		
2.	<input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.		
3.	<input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).		
4.	<input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19 <sup>th</sup> month from the earliest claimed priority date.		
5.	<input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). b. <input checked="" type="checkbox"/> has been transmitted by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)		
6.	<input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).		
7.	<input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau) b. <input type="checkbox"/> have been transmitted by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made.		
8.	<input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).		
9.	<input checked="" type="checkbox"/> An oath or Declaration of the Inventor(s) (35 U.S.C. 371(c)(4)). <i>(Unexecuted)</i>		
10.	<input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
Items 11 to 16 below concern document(s) or information included:			
11.	<input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.		
12.	<input type="checkbox"/> An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.		
13.	<input checked="" type="checkbox"/> A <b>FIRST</b> Preliminary Amendment. A <b>SECOND</b> or <b>SUBSEQUENT</b> Preliminary Amendment.		
14.	<input type="checkbox"/> A substitute specification.		
15.	<input type="checkbox"/> A change of Power of Attorney and/or address letter.		
16.	<input type="checkbox"/> Other items or information:		
EXPRESS MAIL mailing label number <u>EV012137377US</u>			
I, <u>Talisha L. Cooper</u> , hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on <u>January 25, 2002</u> and is addressed to "Box PCT, Commissioner for Patents, Washington, DC 20231"			
			

U.S. APPLICATION NO. (if known, see 37CFR 1.5) <b>10/069081</b>	INTERNATIONAL APPLICATION NO PCT/EP00/07204	ATTORNEY'S DOCKET NUMBER DHN/322/PC/US
		CALCULATIONS PTO USE ONLY
17. <input checked="" type="checkbox"/> The following fees are submitted:		
<b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):</b>		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37CFR 1.445 (a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... \$		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... \$		
International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33 (1) - (4) ..... \$		
International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims satisfied provisions of PCT Article 33 (1) - (4) ..... \$		
<b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b> \$ 890.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)). \$		
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total claims	20 - 20 =	0
Independent claims	2 - 3 =	0
<b>MULTIPLE DEPENDENT CLAIM(S) (if applicable)</b>		+\$
<b>TOTAL OF ABOVE CALCULATIONS =</b>		\$ 890.00
Reduction of $\frac{1}{2}$ for filing by small entity, if applicable.		\$ 445.00
<b>SUBTOTAL =</b>		\$ 445.00
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +		\$
<b>TOTAL NATIONAL FEE =</b>		\$ 445.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property. +		\$
<b>TOTAL FEES ENCLOSED =</b>		\$ 445.00
		Amount to be refunded: \$
		Charged: \$
a. <input checked="" type="checkbox"/> A check in the amount of \$ 445.00 to cover the above fees is enclosed.		
b. <input type="checkbox"/> Please charge my Deposit Account Number 16-2563 in the amount of \$ _____ to cover the above fees. A <i>duplicate copy of this sheet is enclosed</i> .		
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 16-2563 A <i>duplicate copy of this sheet is enclosed</i> .		
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.		
SEND ALL CORRESPONDENCE TO:		
Guy D. Yale, Esq.		
Alix, Yale & Ristas, LLP 750 Main Street, Suite 1400 Hartford, Connecticut 06103		
SIGNATURE Guy D. Yale		
NAME		
29,125		
REGISTRATION NUMBER		

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of David Foster, et al

Serial No.: International PCT/EP00/07204  
Filing Date: Application No.: International Filing Date: July 26, 2000  
For: Orthopedic Bone Cement Mixing Container

Commissioner for Patents  
Washington, DC 20231

Sir:

**PRELIMINARY AMENDMENT**

Before calculating the filing fee and examining the application, please enter the following amendments:

The amendments are made with reference to the PCT application as officially published on July 26, 2000 as International Publication Number WO 01/06963 A2.

In the Specification:

After the title, insert —This application is the U.S. National Phase of International Application No. PCT/EP00/07204, filed on July 26, 2000.

**BACKGROUND OF THE INVENTION—**

Page 4, after line 22, insert —SUMMARY OF THE INVENTION—

Page 6, after line 7, insert —BRIEF DESCRIPTION OF THE DRAWINGS—

Page 6, after line 17, insert —DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS—

In the claims:

Please amend claims 4 through 9 as follows:

4. (amended) An apparatus as claimed in claim 2 [or 3], wherein the inner housing is attached to the cap by means of a snap fit arrangement.

5. (amended) An apparatus as claimed in [any preceding] claim 1, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.

6. (amended) An apparatus as claimed in [any preceding] claim 1, wherein said inner housing is less rigid than said outer housing.

7. (amended) An apparatus as claimed in [any preceding] claim 1, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

8. (amended) An apparatus as claimed in [any preceding] claim 1, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

9. (amended) An apparatus as claimed in [any preceding] claim 1, further comprising means allowing gas to circulate around the cement contained in the inner housing.

Please add new claims 11 through 20 as follows:

11. An apparatus as claimed in claim 3, wherein the inner housing is attached to the cap by means of a snap fit engagement.

12. An apparatus as claimed in claim 2, wherein said inner housing is provided with a feather tip seal for sealing against said housing.

13. An apparatus as claimed in claim 2, wherein said inner housing is less rigid than said outer housing.

14. An apparatus as claimed in claim 2, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

15. An apparatus as claimed in claim 2, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

16. An apparatus as claimed in claim 2, further comprising means allowing gas to circulate around the cement contained in the inner housing.

17. An apparatus as claimed in claim 3, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.

18. An apparatus as claimed in claim 3, wherein said inner housing is less rigid than said outer housing.

19. An apparatus as claimed in claim 3, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

20. An apparatus as claimed in claim 3, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

**A CLEAN COPY OF THE AMENDED AND NEWLY ADDED CLAIMS  
IS ENCLOSED.**

**In the Abstract:**

Please enter the Abstract of the Disclosure on the separate sheet enclosed herewith.

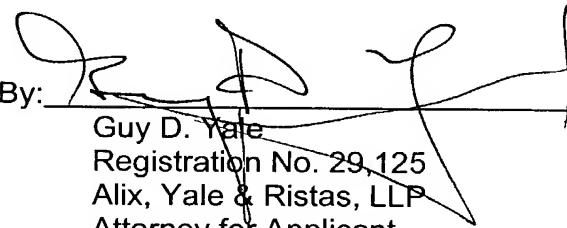
**REMARKS**

Applicant has amended the application to conform same to U.S. patent practice. Multiple dependent claims have been eliminated. An Abstract of the Disclosure on a separate sheet has been enclosed.

Applicant respectfully requests that the amendments be entered prior to calculation of the filing fee and examination of the application.

Respectfully Submitted,

David Foster, et al

By:   
Guy D. Yale  
Registration No. 29,125  
Alix, Yale & Ristas, LLP  
Attorney for Applicant

Date: January 25, 2002  
750 Main Street  
Hartford, CT 06103-2721  
(860) 527-9211  
Our Ref: DHN/322/PC/US

GDY/tlc

**CLEAN COPY OF AMENDED CLAIMS**

4. An apparatus as claimed in claim 2, wherein the inner housing is attached to the cap by means of a snap fit arrangement.

5. An apparatus as claimed in claim 1, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.

6. An apparatus as claimed in claim 1, wherein said inner housing is less rigid than said outer housing.

7. An apparatus as claimed in claim 1, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

8. An apparatus as claimed in claim 1, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

9. An apparatus as claimed in claim 1, further comprising means allowing gas to circulate around the cement contained in the inner housing.

11. An apparatus as claimed in claim 3, wherein the inner housing is attached to the cap by means of a snap fit engagement.

12. An apparatus as claimed in claim 2, wherein said inner housing is provided with a feather tip seal for sealing against said housing.

13. An apparatus as claimed in claim 2, wherein said inner housing is less rigid than said outer housing.

14. An apparatus as claimed in claim 2, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

15. An apparatus as claimed in claim 2, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

16. An apparatus as claimed in claim 2, further comprising means allowing gas to circulate around the cement contained in the inner housing.

17. An apparatus as claimed in claim 3, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.

18. An apparatus as claimed in claim 3, wherein said inner housing is less rigid than said outer housing.

19. An apparatus as claimed in claim 3, wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

20. An apparatus as claimed in claim 3, wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

## ABSTRACT OF THE DISCLOSURE

The invention discloses a pre-filled orthopedic cement container in which the cement can also be mixed. The container comprises an outer housing defining the mixing chamber and an inner housing containing the cement prior to mixing. The inner housing is removable, prior to mixing, in such a way that the cement powder remains in the mixing chamber for mixing.

3 | P7 | P - 1 -  
Orthopaedic Bone Cement  
Mixing Container

This invention relates to a container in which  
5 orthopaedic bone cement is mixed.

Orthopaedic bone cement is used throughout the  
world to secure hip, knee and other metallic prostheses  
in an appropriate anatomical position.

10 Many different systems are available for mixing  
orthopaedic bone cement and the type of apparatus  
selected will depend on the personal preferences of the  
doctor or nurse mixing the cement, as well as the amount  
of cement being mixed and the type of materials being  
used.

15 Essentially, orthopaedic cement is made up of a  
powder component, e. g. polymethylmethacrylate powder,  
and a monomer, eg. g. methylmethacrylate monomer liquid,  
generally provided in an ampoule which is broken and  
added to the powder. The two components are then  
20 thoroughly mixed to provide a malleable cement which can  
be manipulated and applied to the appropriate bone  
parts, during surgery.

25 In order to avoid the cement becoming brittle, it  
is essential that the two components are very thoroughly  
mixed together and no 'dry' or 'dead' spots remain.  
Furthermore, as most cements set fairly quickly, it is  
important that the mixing can be quickly and easily  
carried out. This is, also, of course important as  
30 surgery should be carried out as quickly as possible for  
the comfort and safety of the patient.

35 Originally, the cement components were mixed, by  
hand, using a bowl and spatula. A theatre nurse would  
mix the appropriate quantities of the two components in  
the bowl and the physician would then take some of the  
mixed cement and mould it to the required shape, before  
inserting it into a preformed cavity or applying it to a  
resected bony surface where the prosthesis is to be

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positioned. Cement may either be applied by hand or may be put into a syringe and applied thereto.

Although mixing in this way is straightforward and convenient, it can have drawbacks.

5 Firstly, free methylmethacrylate fumes are emitted from the mixture. It is desirable to remove these fumes, or prevent them from escaping into the atmosphere, since they have an unpleasant odour and may be harmful to operating room and personnel. The fumes 10 are known to cause nausea and giddiness and are generally objectionable, particularly to the nurses who actually carry out the mixing.

15 Secondly, a very high mixing efficiency is required to produce a homogenous cement material. During the mixing process, air is naturally introduced into the mixture since air is inherently existent within the powder and also in and around the mixing vessel. Air bubbles are also produced by the 'boiling off' of monomer which occurs during the mixing process. The 20 introduction of air produces a weak cement and, since the joint must usually support a heavy load, it is important to reduce the amount of air in the mixture as much as possible in order to improve the mechanical strength of the cement material.

25 Furthermore, this mixing process can be slow and result in the cement beginning to dry out before it has been used and can require the patient to be on the operating table longer than desirable. Where 30 particularly viscous cements are used, mixing in this way can also be rather tiring for the theatre nurse and can, in some cases, lead to muscle fatigue and strain.

35 A variety of systems is now available to simplify and improve the mixing of bone cement and to overcome the problems mentioned above. Many of these include the application of a vacuum to a sealed mixing chamber which removes air from the mixture and avoids weak spots. This results in a greatly improved cement.

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One such mixing device is the bowl mixer forming the subject of European Patent No. 0616552. This system is preferred by many users as it is small and convenient to use and the mixing action is similar to that carried out in the above described manual bowl mixing technique and is one with which nurses are generally familiar.

Another mixing system is described in European Patent No. 0744991. In this arrangement, the cement is mixed in a cylindrical mixing chamber. The mixing mechanism comprises paddles rotatably mounted within the chamber. The paddles are rotated around the chamber by means of a 'barley twist' mechanism so that the user merely has to push the handle up and down, to cause rotation of the paddle. Furthermore, once the cement is mixed, this system can be converted into a syringe type dispenser by addition of a nozzle and plunger. There is thus no need to remove the mixed cement from the mixing chamber and transfer it to a dispenser.

Other similar mixing arrangements are known.

In all of these systems, the cement components need to be put into the mixing chamber. Generally, the nurse is provided with the cement powder, in a bag, and monomer ampoule. These are opened by the nurse, manually, and are introduced into the mixing chamber or bowl by means of funnels.

One problem is that when cutting open the cement powder bag and inserting the powder via the funnel, there is a certain degree of wastage due to spillage and cement clinging to the funnel. Furthermore, the opening and pouring of the cement powder caused a powder cloud which, within the regulated confines of the operating theatre, is unpleasant and may even have adverse effects on the theatre personnel.

These problems become more acute when time is very short and the mixing must be done extremely quickly, or with inexperienced theatre personnel.

One solution which has been considered is to

provide a pre-filled mixing apparatus, wherein the disposable mixer, for example a bowl mixer or syringe mixer as described above, is supplied already containing the cement powder in the mixing chamber. This generally 5 makes things much easier for the theatre nurse when needing to mix the cement quickly during an operation.

However, tests have shown that if the cement powder is housed within the mixing chamber or bowl and contained therein by means of a cap, the powder moves 10 about, particularly during transportation, and covers the entire internal surface area of the mixing chamber and the lid. When the mixing is carried out, with the introduction of the monomer, unmixed powder remains at the top of the mixing vessel due to the monomer not 15 wetting all of the walled surface, and the mixing paddle not reaching the very fine layer of powder on the walls and at the top of the chamber. Thus, powder is wasted and 'dry' spots occur, resulting in brittle cement which can have adverse consequences.

20 The aim of the present invention is to provide a pre-filled orthopaedic cement mixing apparatus in which the above mentioned problems are overcome.

According to one aspect of the present invention, 25 there is provided an apparatus for containing and mixing orthopaedic cement, the apparatus containing an outer housing defining a mixing chamber and an inner housing containing the cement prior to mixing, wherein the inner housing is removable from the outer housing such that the cement remains in the mixing chamber.

30 In accordance with another aspect of the invention, there is provided a method of providing and mixing of orthopaedic cement comprising sealing said cement in an inner housing; disposing said inner housing within an outer housing which defines a mixing chamber; removing 35 the inner housing, leaving the cement in the mixing chamber for mixing.

The present invention may be incorporated into any

known cement mixing arrangements including the bowl mixer and syringe mixer described above. It may also be incorporated in mixing bowls where the mixing is carried out simply using a spatula etc.

5 The inner housing may be removable from the outer housing in any way, for example it may be in the form of a bag which is merely lifted out by the user, which opens on removal to drop the cement powder into the mixing chamber. In the most preferred embodiment, 10 however, the inner housing is attached to or formed integrally with a lid provided on the container. The inner housing and the lid may, for example, be attached to each other by a snap fit arrangement or, indeed, by any other means of attachment. Thus, when the cement is 15 to be mixed, the lid is removed by the user and as the lid is removed, it takes with it the inner housing.

20 To provide a secure container during transportation etc., the lid is preferably attached to the outer housing by means of a screw thread. Seals may also be provided.

25 The inner housing may be made of any materials suitable for containing the cement powder. Preferably, the material of which the inner housing is made is less rigid than that of the outer housing. This allows the inner housing to be compressed against the outer housing to provide a good seal at the open end of the inner housing.

30 It is important that, prior to removal of the inner housing, the cement is securely contained within the housing and, therefore, the 'open' end of the inner housing should form a seal with the outer housing or should be closed after filling.

35 Thus, in one embodiment, not shown, the inner housing has an open end into which the cement is inserted. This open end is then closed by any suitable means and the inner housing is placed within the outer housing in such a manner that when the inner housing is

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removed from the outer housing, the inner housing is opened or ruptured allowing the cement to fall out into the inner housing.

5 In the most preferred arrangement, the inner housing, at the open end, is provided with a feather seal edge which provides a seal against the base or lower part of the outer housing.

10 Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings.

15 Fig. 1 shows a cross-section of a mixing system according to the present invention.

20 Figs. 2A-2D show the different stages of inserting and mixing the cement using the apparatus shown in Fig.

25 1.

Fig. 3 shows an alternative embodiment of the present invention.

20 The embodiment shown in Fig. 1 uses a mixing system such as described in EP 0744991. This comprises a cylindrical mixing chamber, in which is arranged a mixing paddle (not shown), rotated by means of a handle connected thereto by a 'barley twist' rod and gear mechanism. The paddle is rotated around the mixing chamber by a pushing and pulling action on the handle. Vacuum is applied to the chamber during the mixing.

25 Once the cement is mixed, the cap and mixing mechanism are removed and replaced by a nozzle. A plunger is applied to the other end of the mixing chamber and is pushed through the chamber, by means of, e. g., a mastic-type gun to eject the mixed cement through the nozzle.

30 This mixing system is modified by the present invention and is provided as a pre-filled system.

35 Thus, the cement is provided in an inner housing 2 which is located in the outer, mixing chamber housing 3.

The inner housing, containing the cement 4, is attached to the cap 5 of the mixing chamber by a snap

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fit arrangement 6. This creates a seal through which the cement powder cannot pass.

Fig. 2A shows how the cement is inserted into the inner housing, via the open end 7 of the housing.

5 The outer housing 3 incorporating the piston and base 8 is then fitted over the cement containing inner housing as shown in Fig. 2D.

10 Guide lips 9 may be provided on the outer surface of the inner housing to assist in the correct positioning of the outer housing relative to the inner housing.

15 The outer housing is then secured to the cap, by means of a screw thread 10, as shown in Fig. 2C. The open end of the inner housing, containing the cement, is provided with a seal 11, preferably a feather seal, which fully seals to the piston part of the outer housing to secure the cement powder within the inner housing. This results in a fully sealed packaged container, containing the cement powder within the inner 20 housing, ready for use. The whole device is then packaged and sterilised for use.

A breather pad (not shown) may be provided on the cap so as to allow gas circulation to the cement.

25 As shown in Fig. 2D, when the cement is to be mixed, the user unscrews the cap 5 from the outer housing 2 and lifts away the cap and the inner housing 3 connected thereto. As the inner housing is lifted away from the base of the outer housing, the cement powder 4 drops out of the inner housing into the mixing chamber 30 1. The cap and inner housing are then discarded and the standard mixing procedure for this type of mixing arrangement is carried out.

35 A similar procedure is used in relation to other mixing arrangements such as the bowl mixer 12 shown in Fig. 3. This may be a bowl as described in EP 0616552. The principle is essentially the same. An inner housing 3', containing the cement powder 4', is attached to the

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lid 5' of the bowl at one end and is sealed 11' to the base of the bowl or the sides of the bowl near its base by means of e. g. a feather seal. In use, the lid 5' and attached inner housing 3' are removed, such that the cement powder 4' drops out of the inner housing into the mixing chamber 1' and mixing is carried out in the usual way.

It is preferable that the inner housing is made of a material which is less rigid than the outer housing. This allows the feather seal edge of the inner housing to be compressed unto the outer housing to provide a secure seal for the cement powder.

In the preferred syringe type arrangement, the inner housing is designed to hold up to 80g of cement powder, i. e. a double mix of cement. In the case of the bowl mixer, preferably, the inner housing can hold up to 120g, i. e. a triple mix of cement.

Because the cement powder is contained within the inner housing until it is to be mixed, and is then dropped out of the housing only into the bottom of the mixing chamber, no cement clings to the upper outer walls of the mixing chamber and so practically all of the cement can be thoroughly mixed, producing a high quality mixed orthopaedic cement.

25

## CLAIMS

1. An apparatus for containing and mixing orthopaedic cement, the apparatus containing an outer housing defining a mixing chamber and an inner housing containing the cement prior to mixing, wherein the inner housing is removable from the outer housing such that the cement remains in the mixing chamber.

2. An apparatus as claimed in claim 1 wherein the outer housing is provided with a cap and wherein the inner housing is attached to said cap such that the cap and inner housing can be removed from the outer housing together.

3. An apparatus as claimed in claim 2 wherein the cap is attached to the outer housing by means of a screw thread.

4. An apparatus as claimed in claim 2 or 3 wherein the inner housing is attached to the cap by means of a snap fit arrangement.

5. An apparatus as claimed in any preceding claim, wherein said inner housing is provided with a feather tip seal for sealing against said outer housing.

6. An apparatus as claimed in any preceding claim wherein said inner housing is less rigid than said outer housing.

7. An apparatus as claimed in any preceding claim wherein said outer housing is in the form of a cylindrical mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

8. An apparatus as claimed in any preceding claim

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wherein said outer housing is in the form of a bowl shaped mixing chamber adapted to be provided with a mixing mechanism comprising a blade arrangement rotatable around said chamber.

5

9. An apparatus as claimed in any preceding claim, further comprising means allowing gas to circulate around the cement contained in the inner housing.

10

10. A method of providing and mixing of orthopaedic cement comprising sealing said cement in an inner housing; disposing said inner housing within an outer housing which defines a mixing chamber; removing the inner housing, leaving the cement in the mixing chamber for mixing.

15

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(81) Designated States (national): AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DB (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

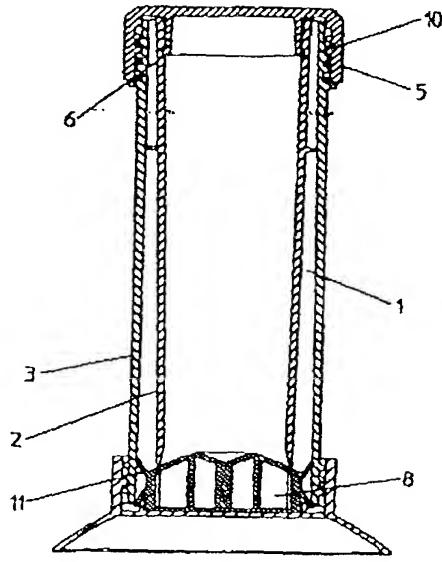
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BB, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

## Published:

— Without international search report and to be republished upon receipt of that report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ORTHOPAEDIC BONE CEMENT MIXING CONTAINER

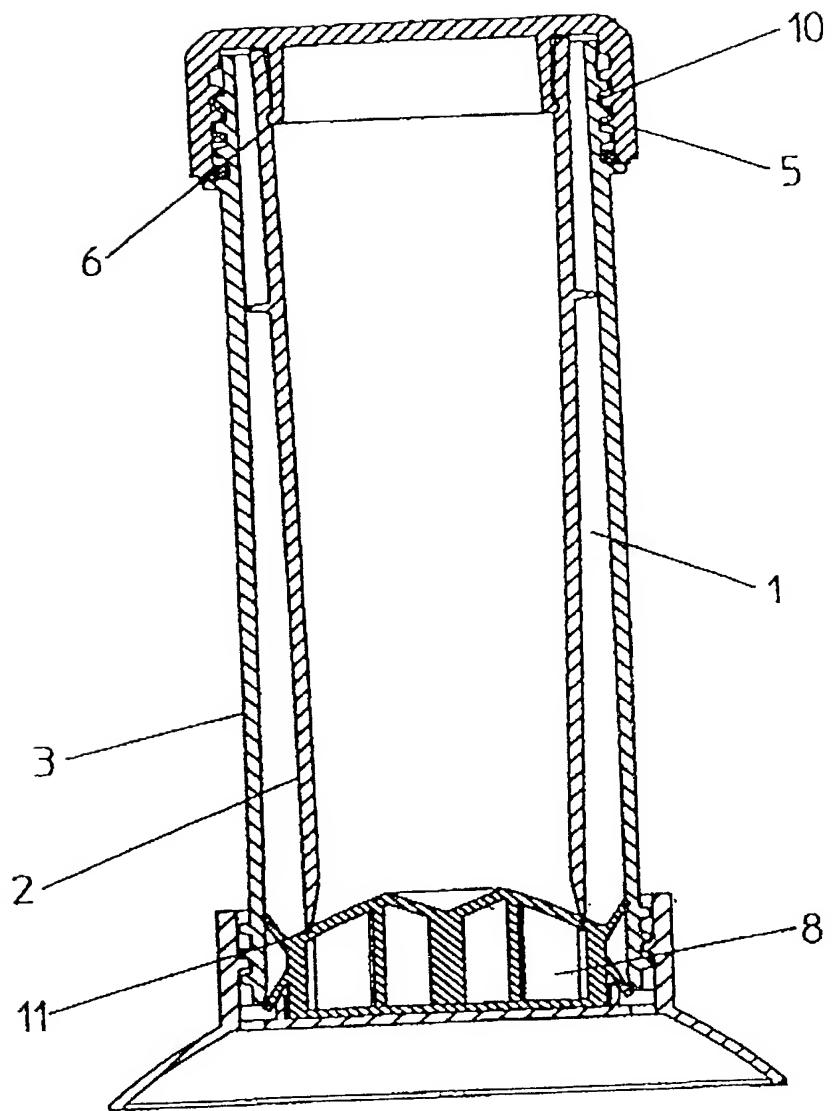


(57) Abstract: The invention discloses a pre-filled orthopaedic cement container in which the cement can also be mixed. The container comprises an outer housing defining the mixing chamber and an inner housing containing the cement prior to mixing. The inner housing is removable, prior to mixing, in such a way that the cement powder remains in the mixing chamber, for mixing.

WO 01/06963 A2

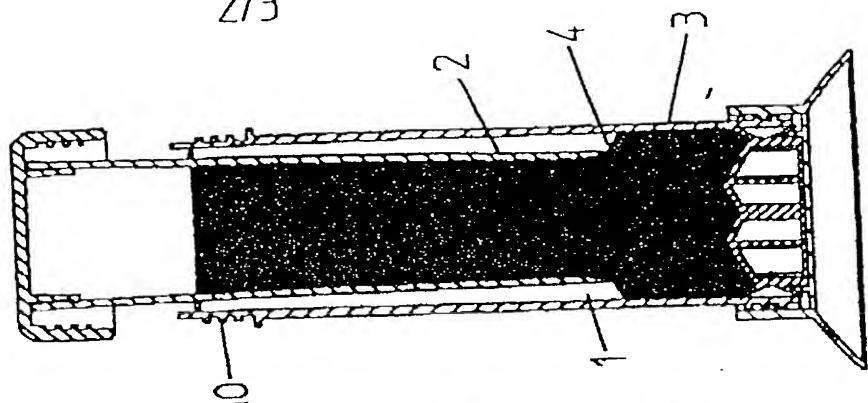
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WO 01/06963

2/3



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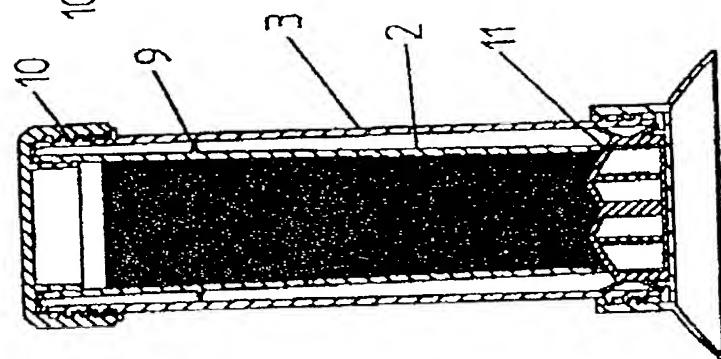


FIG 2C

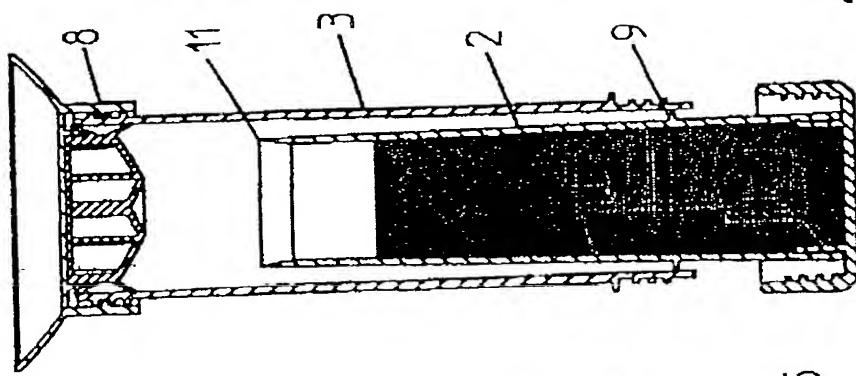


FIG 28

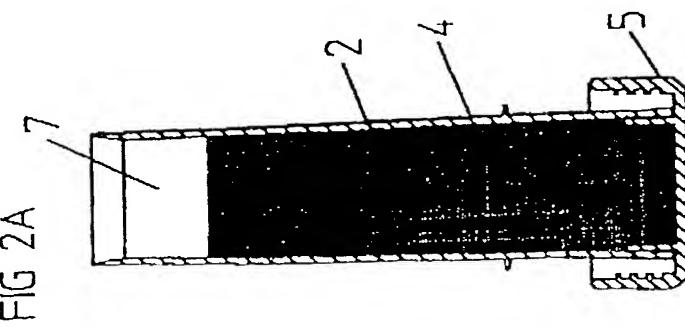


FIG 2A 7

3/3

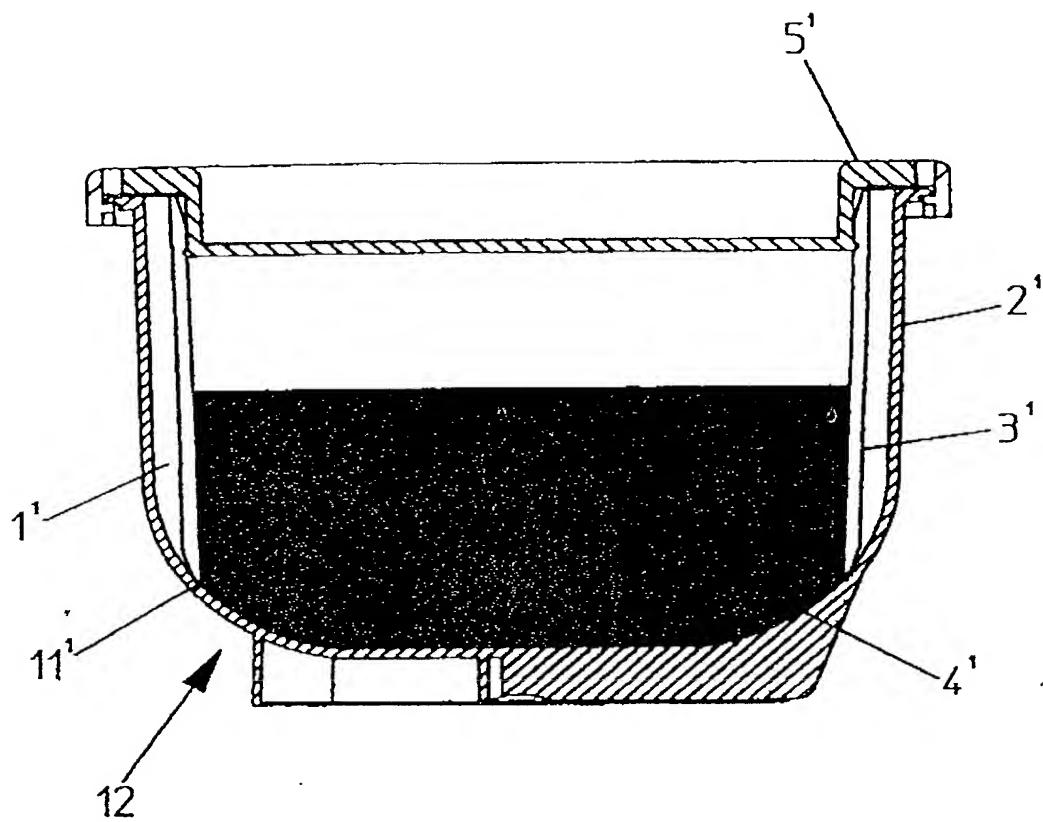


FIG 3

Type a plus sign (+) inside this box → [+]

0010/PTO Rev. 6/95	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket	DHN/322/PC/US
		First Named Inventor	David Foster, et al
COMPLETE IF KNOWN			
		Application Number	
		Filing Date	
		Group Art Unit	
		Examiner Name	

## DECLARATION

Declaration Submitted  
with Initial Filing

Declaration Submitted  
after Initial Filing

As an above named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Orthopedic Bone Cement Mixing Container

(Title of the Invention)

the specification of which

is attached hereto

OR

was filed on (MM/DD/YYYY) July 26, 2000 as United States Application or PCT International Application Number PCT/EP00/07204 and was amended on (MM/DD/YYYY) \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Codes of Federal Regulations, §1.56.

I hereby claim foreign priority under Title 35, United States Code § 119 (a)-(d) or § 365 (b) of any foreign application(s) for patent or inventor's certificate, or § 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Numbers	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Copy Attached Yes	Copy Attached No
9917624.0	United Kingdom	July 27, 1999	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Additional foreign application numbers are listed on a supplemental priority sheet attached hereto:

I hereby claim the benefit under Title 35, United States Code § 119 (e) of any United States provisional application(s) listed below:

Application Number(s)	Filing Date (MM/DD/YY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority sheet attached hereto.

## DECLARATION

Page 2

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365(c) of any PCT International application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Title Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

Additional U.S. or PCT International application numbers are listed on a supplementary priority sheet attached hereto:

As a named inventor, I hereby appoint the registered practitioners associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office therewith, and direct that all correspondence be addressed to that Customer Number:

Firm Name:

Alix, Yale & Ristas, LLP

Customer Number:

002543

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor								
<input type="checkbox"/> A petition has been filed for this unsigned inventor								
Given Name	David	Middle Initial		Family Name	Foster		Suffix	
Inventor's Signature						Date		
RESIDENCE: City	Woodstock	State		Country	United Kingdom		Citizenship	United Kingdom
POST OFFICE ADDRESS	49 Oxford Street							
City	Woodstock	State		Zip	OX20 1TJ	Country	United Kingdom	Applicant Authority
Name of Additional Joint Inventor, if any:								
<input type="checkbox"/> A petition has been filed for this unsigned inventor								
Given Name	Anthony	Middle Initial		Family Name	Jones		Suffix	
Inventor's Signature						Date		
RESIDENCE: City	Abingdon	State	Oxon	Country	United Kingdom		Citizenship	United Kingdom
POST OFFICE ADDRESS	22 Bourton Road							
City	Abingdon	State	Oxon	Zip	OX14 1LF	Country	United Kingdom	Applicant Authority
<input checked="" type="checkbox"/> Additional inventors are being named on supplemental sheet(s) attached hereto.								

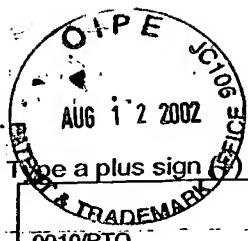
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PAGE 3

## DECLARATION

### ADDITIONAL INVENTOR(S) Supplemental Sheet

Name of Additional Joint Inventor, if any:					<input type="checkbox"/> A petition has been filed for this unsigned inventor				
Given Name	Rebecca		Middle Initial		Family Name	Eveleigh		Suffix	
Inventor's Signature						Date			
RESIDENCE: City	Cheltenham		State		Country	United Kingdom		Citizenship	United Kingdom
POST OFFICE ADDRESS	10 Stow Court, Gloucester Road								
City	Cheltenham		State		Zip	GL51 6ND	Country	United Kingdom	Applicant Authority
Name of Additional Joint Inventor, if any:					<input type="checkbox"/> A petition has been filed for this unsigned inventor				
Given Name			Middle Initial		Family Name			Suffix	
Inventor's Signature						Date			
RESIDENCE: City			State		Country		Citizenship		
POST OFFICE ADDRESS									
City			State		Zip		Country		Applicant Authority
Name of Additional Joint Inventor, if any:					<input type="checkbox"/> A petition has been filed for this unsigned inventor				
Given Name			Middle Initial		Family Name			Suffix	
Inventor's Signature						Date			
RESIDENCE: City			State		Country		Citizenship		
POST OFFICE ADDRESS									
City			State		Zip		Country		Applicant Authority
Name of Additional Joint Inventor, if any:					<input type="checkbox"/> A petition has been filed for this unsigned inventor				
Given Name			Middle Initial		Family Name			Suffix	
Inventor's Signature						Date			
RESIDENCE: City			State		Country		Citizenship		
POST OFFICE ADDRESS									
City			State		Zip		Country		Applicant Authority
<input type="checkbox"/> Additional inventors are being named on supplemental sheet(s) attached hereto									



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0010/PTO Rev. 6/95  <b>DECLARATION</b>  <input checked="" type="checkbox"/> Declaration Submitted with Initial Filing <input type="checkbox"/> Declaration Submitted after Initial Filing	Attorney Docket	DHN/322/PC/US
	First Named Inventor	David Foster, et al
	<b>COMPLETE IF KNOWN</b>	
	Application Number	
	Filing Date	
	Group Art Unit	
Examiner Name		

As an above named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**Orthopedic Bone Cement Mixing Container**

(Title of the Invention)

the specification of which

is attached hereto

OR

was filed on (MM/DD/YYYY) July 26, 2000 as United States Application or PCT International Application Number PCT/EP00/07204 and was amended on (MM/DD/YYYY) \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-mentioned specification, including the claims, as amended by any amendment specifically referred to above.

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I hereby claim foreign priority under Title 35, United States Code § 119 (a)-(d) or § 365 (b) of any foreign application(s) for patent or inventor's certificate, or § 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT International application having a filing date before that of the application on which priority is claimed.

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I hereby claim the benefit under Title 35, United States Code § 119 (e) of any United States provisional application(s) listed below:

Application Number(s)	Filing Date (MM/DD/YY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority sheet attached hereto.

## DECLARATION

Page 2

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365(c) of any PCT-International application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Title Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

Additional U.S. or PCT International application numbers are listed on a supplementary priority sheet attached hereto:

As a named inventor, I hereby appoint the registered practitioners associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office therewith, and direct that all correspondence be addressed to that Customer Number:

Firm Name:

Alix, Yale &amp; Ristas, LLP

Customer Number:

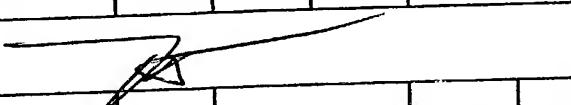
002543

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

A petition has been filed for this unsigned inventor

Name of Sole or First Inventor

Given Name	David	Middle Initial		Family Name	Foster	Suffix	
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Inventor's Signature				Date	X 28/6/02
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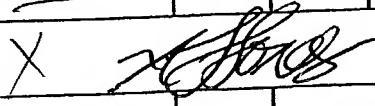
RESIDENCE: City	Woodstock	State		Country	United Kingdom	Citizenship	United Kingdom
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POST OFFICE ADDRESS	49 Oxford Street						
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City	Woodstock	State		Zip	OX2 1TJ	Country	United Kingdom	Applicant Authority	
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Name of Additional Joint Inventor, if any:	A petition has been filed for this unsigned inventor						
--	--	--	--	--	--	--	--

Given Name	Anthony	Middle Initial		Family Name	Jones	Suffix	
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Inventor's Signature				Date	X 5/7/02
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RESIDENCE: City	Abingdon	State	Oxon	Country	United Kingdom	Citizenship	United Kingdom
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POST OFFICE ADDRESS	22 Bourton Road						
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City	Abingdon	State	Oxon	Zip	OX14 1LF	Country	United Kingdom	Applicant Authority	
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Additional inventors are being named on supplemental sheet(s) attached hereto.

Type a plus sign (+) inside this box → [+]

PAGE 3

## DECLARATION

## ADDITIONAL INVENTOR(S) Supplemental Sheet

Name of Additional Joint Inventor, if any:					<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name	Rebecca	Middle Initial		Family Name	Eveleigh		Suffix	
Inventor's Signature	<i>X R. Eveleigh</i>					Date	<i>X 2nd July 2002</i>	
RESIDENCE: City	Cheltenham	State		Country	United Kingdom	Citizen	United Kingdom	
POST OFFICE ADDRESS	10 Stow Court, Gloucester Road							
City	Cheltenham	State		Zip	GL51 6ND	Country	United Kingdom	Applicant Authority
Name of Additional Joint Inventor, if any:					<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name		Middle Initial		Family Name			Suffix	
Inventor's Signature						Date		
RESIDENCE: City		State		Country		Citizen		
POST OFFICE ADDRESS								
City		State		Zip		Country		Applicant Authority
Name of Additional Joint Inventor, if any:					<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name		Middle Initial		Family Name			Suffix	
Inventor's Signature						Date		
RESIDENCE: City		State		Country		Citizen		
POST OFFICE ADDRESS								
City		State		Zip		Country		Applicant Authority
Name of Additional Joint Inventor, if any:					<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name		Middle Initial		Family Name			Suffix	
Inventor's Signature						Date		
RESIDENCE: City		State		Country		Citizen		
POST OFFICE ADDRESS								
City		State		Zip		Country		Applicant Authority
<input type="checkbox"/> Additional inventors are being named on supplemental sheet(s) attached hereto								